UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,386	03/19/2004	Michael L. Garrison	1-37234	7250

42715 7590 04/27/2007
DUNLAP, CODDING & ROGERS, P.C.
P.O. BOX 16370
OKLAHOMA CITY, OK 73113

EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,386	GARRISON ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-14 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-14 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 19 February 2007. The examiner acknowledges the amendment to Claim 1.

In regards to the Information Disclosure Statement submitted on 24 March 2005, it is not necessary for applicant to resubmit the IDS or to pay of a fee. The examiner was merely suggesting the applicant send legible copies of the non-patent literature documents for reference.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kirkman** (U.S. Patent No. **6,071,263**).

Claim 1: Kirkman discloses a method for delivering and deploying an expandable intraluminal device, providing a delivery system comprising an elongate member **4** having proximal and distal ends, and the expandable intraluminal medical device **154** circumferentially disposed about a portion of the elongate member **4** (Figure 10A and 10B). The distal end of the elongate member **4** is inserted into a body vessel, and the distal end of the elongate member **4** is advanced **4** through the body vessel to the desired point of

treatment. A portion of the elongate member is spaced from a wall surface of the blood vessel, and the expandable intraluminal medical device is deployed from the elongate member after the elongate member has been spaced from a wall surface of the body surface. Lastly, the elongate member is withdrawn from the body vessel (col. 12, lines 26-28 and col. 13, lines 5-50).

Claim 2: Kirkman also discloses that the step of spacing a portion of the elongate member from a wall surface of the body vessel comprises spacing a portion of the elongate member that includes the expandable intraluminal device **154**, which lies at the catheter tip **8** (col. 12, lines 55-59).

Claim 3: Kirkman discloses that the elongate member **2** defines a lumen and the delivery system further comprises an ancillary delivery device **9** having a means for spacing a portion of the elongate member **2** from a wall surface of a body vessel

(col. 3, lines 50-53 and col. 6, lines 43-47).

Claim 4: Kirkman discloses the means for spacing comprising a basket **9** formed from four wires **12** and having expanded and collapsed configurations (Figures 2A-2B and col. 8, lines 15-19).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **St. Germain et al.** (U.S. Patent No **5,534,007**).

Claim 8: Kirkman discloses the claimed steps except for the delivery system further comprising a sheath that is circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal device comprises retracting the sheath from a position about the expandable intraluminal medical device

St. Germain et al. teaches deployment catheter for an expandable intraluminal device that comprises a sheath **40** that is circumferentially disposed about and movable along an elongate member **5**, and the step of deploying the expandable intraluminal device **35** comprises retracting the sheath **40** from a position about the expandable intraluminal medical device **35** (Figure 1 and col. 3, lines 27-36). St. Germain et al. teaches that the use of the sheath **40** retains the expandable intraluminal device **35** and protects the vessel wall (col. 3, lines 36-38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a sheath that is circumferentially disposed about the elongate member and retracting the sheath in the step of deploying the expandable intraluminal device, as taught by St. Germain et al., to Kirkman in order to retain the expandable intraluminal device before deployment and to protect the vessel wall from injury.

Claim 9: Kirkman discloses the elongate member **2** defining a lumen and the delivery system further comprising an ancillary delivery device **9** disposed within the lumen, the ancillary delivery device having a means for spacing a portion of the elongate member from a wall surface of a body vessel (Figures 2A and 2B).

Claims 10-11: Kirkman discloses the step of spacing a portion of the elongate member from a wall surface of the body vessel which comprises activating the means for spacing, which includes retracting the sheath from a position about the means for spacing (col. 8, lines 10-19).

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 12: Kirkman discloses the claimed steps except for the expandable intraluminal medical device comprising a prosthetic venous valve

Pavcnik et al. teaches an intraluminal venous valve **43** that is deployed within the blood vessel and exerts force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6, page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the device of Kirkman, since it was known in the art

that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**), as applied to Claim 13 above, and further in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 18: Kirkman discloses the claimed device except for the expandable intraluminal device comprising a prosthetic venous valve.

Pavcnik et al. teaches an intraluminal venous valve **43** that is deployed within the blood vessel and exerts a force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6 and page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a prosthetic venous valve device, as taught by Pavcnik et al., to the device of Kirkman, since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

7. Claims 13-14 are U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **Levine et al.** (U.S. Pub. No. **20040087965**).

Claim 13: Kirkman discloses the claimed device, including a delivery system comprising an elongate member **4** having proximal and distal ends and defining a

first lumen, an expandable intraluminal medical device **154** circumferentially disposed about a portion of the elongate member (Figure 10A and 10B), a sheath circumferentially disposed about the elongate member and the expandable intraluminal device, the sheath being movable along the elongate member (col. 8, lines 3-19), and an ancillary delivery device **9** having a basket formed from at least two wire members **156**, **158**, **160** and having expanded and collapsed configurations, except for the ancillary delivery device disposed in a first lumen and having a basket formed from at least two wire members **156**, **158**, **160** and having expanded and collapsed configurations, wherein the basket is in the collapsed configuration when disposed in the first lumen and is in the expanded configuration when not disposed in the first lumen (col. 3, lines 50-53 and col. 6, lines 43-37, and col. 13, lines 5-50).

Levine et al. teaches an ancillary delivery device having a basket **104** in the collapsed configuration when disposed in a first lumen **114** of **102** and is in the expanded configuration when not disposed in the first lumen (Figure 4F, page 3, paragraphs 37 and 40). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kirkman by providing a basket that collapses into a first lumen and is expanded when not disposed in a first lumen, as taught by Levine et al., since it was known in the art that expandible/collapsible mechanisms are often used in deploying devices since they are readily actuated and withdrawn by the surgeon and effectively facilitate deployment of intraluminal devices.

Claim 14: Kirkman discloses the claimed device except for the at least two wire members comprising flat wire.

Levine et al. teaches wire members **104** comprising flat wire (page 3, paragraph 37). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Kirkman by using flat wire, as taught by Levine et al. since it was known in the art that flat wire would provide more surface area and therefore better contact or engagement with surfaces.

Response to Arguments

8. Applicant's arguments filed 19 February 2007 have been fully considered but they are not persuasive.

Applicant argues that the device and method of Kirkman is physically incapable of performing the spacing and deployment steps separately in regards to the rejection of Claims 1-4. The examiner disagrees. The initial spacing step is achieved by the connecting wires **156, 158, 160** spacing a portion of the elongate member **4** from a wall surface of a body vessel and the subsequent deploying step is achieved by inflating a balloon **162** to expand the intraluminal device **154** and position it against the blood vessel while the connecting wires, which may have "prestressed breakaway points," separate the intraluminal device from the elongate member, which are in fact separate steps (Figures 10A-10B, col. 13, lines 5-36), as maintained above.

Applicant's arguments with respect to Claim 13 have been considered but are moot in view of the new ground(s) of rejection.

In regards to Claims 8-12 and 18 the applicant argues that St. Germain, Pavcnik, and Levine fail to disclose the deficiencies of Kirkman and that there is no suggestion to combine the references. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. As maintained above, it would have been obvious to modify Kirkman with St. Germain since it was known in the art that sheaths protect tissue from injury by retaining devices in deployment, and with Pavcnik since it was known in the art that a intraluminal delivery system may deploy any suitable device such as a prosthetic venous valve, and lastly with Levine, since it was known in the art that expandible/collapsible mechanisms are often used in deploying devices and flat wire provides more surface area and better contact with surfaces.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER